

Claim Rejections-35 U.S.C. §102

Claims 1-3, 6, 7, and 29 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,083,222 issued to Klein, et al. (“Klein”). Applicant respectfully traverse these rejections, since Klein does not disclose each and every element required by these claims.

With regard to independent claim 1, the Examiner states that the intravascular catheter disclosed in Klein includes a relatively stiff hollow catheter body 14, and therefore must have a rigid proximal portion. However, merely because Klein describes the proximal portion of the catheter body 14 as being relatively stiff, does not mean that it is “rigid” within the meaning of the claimed invention. That is, by using the qualifier “relatively,” it is clear that Klein is merely describing the catheter body 14 as being relatively rigid in comparison to other portions of the catheter, e.g., the flexible distal portion 18. Indeed, Fig. 4 of Klein illustrates the proximal end of the catheter body 14 as not being rigid, but rather quite flexible to facilitate its introduction into the vasculature of the patient. Thus, the proximal portion of the catheter body 14 is not disclosed in Klein as being rigid, as required by claim 1.

With regard to independent claim 29, the Examiner essentially states that the apparatus of Klein is inherently capable of performing the recited method claim. Applicant disagrees. The fact that it is possible to perform an undisclosed process with a prior art device does not mean that the process is anticipated by the prior art device or the disclosure thereof. The Examiner should note that “under the principles of inherency, if a prior art device, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art device.” (See M.P.E.P. §2112.02)(emphasis added). While it may be possible for the gripping members of the Klein device to grasp tissue therebetween in certain situations, in the normal and usual operation of the Klein device, the completely open gripping

members are pressed against the myocardial tissue to increase the normal force 128, as illustrated in Fig. 4B. Thus, tissue is not necessarily placed between the gripping members during the normal and usual operation of the Klein device, and in fact, is not even disclosed as being desirable. Klein does not inherently disclose the process recited in claim 29.

Thus, Applicant submits that claims 1-3, 6, 7, and 29 are not anticipated by Klein, and as such, respectfully requests withdrawal of the §102 rejections of these claims.

Claim Rejections-35 U.S.C. §103

Claims 1-5, 7-37, and 39 stand rejected under 35 U.S.C. §103 as being obvious over U.S. Patent No. 4,483,562 issued to Schoolman ("Schoolman") in view of U.S. Patent No. 6,152,923 issued to Ryan ("Ryan"). Applicant respectfully traverses these rejections, since neither of these references, alone or in combination, discloses, teaches, or suggests the combination of elements required by these claims.

Claims 1-5, 7-18, 29-33, and 43-45

The Examiner concludes that it would have been obvious to incorporate the electrodes disclosed in Ryan with the clamping device described in Schoolman. In support of this conclusion, the Examiner indicated that Applicant was arguing that Ryan is not analogous prior art. However, Applicant was not arguing that Ryan is non-analogous prior art. Rather, Schoolman is non-analogous prior art.

Applicant agrees with the Examiner that a prior art reference must either be in the field of applicant's endeavor or be reasonably pertinent to the particular problem with which the Applicant was concerned in order to rely upon it as a basis for rejection of the claimed invention. However, Schoolman does not fall into either of these categories.

In particular, Applicant's field of endeavor is directed to tissue ablation devices and methods.

In contrast, Schoolman's field of endeavor is directed to tools having flexible shafts (see col. 1, lines 6-10). Schoolman briefly mentions using clamping mechanisms to retain tissue, but nonetheless, Schoolman's field of endeavor is not directed to tissue ablation or any type of tissue treatment.

Schoolman is also not reasonably pertinent to the particular problem with which Applicant was concerned, which was to obviate the need to pin point an incision point or the need to use multiple ablation clamps having different shapes during a single operation (see page 2, lines 1-11). In contrast, with regard to surgical operations, Schoolman attempts to solve the problem of freeing the hands of a surgeon or medical assistant during an operation (see col. 1, lines 12-25). In sum, one of ordinary skill in the art of tissue ablation would not look to Schoolman to solve the problem with which Applicant was concerned, and thus, Schoolman is not analogous art that the Examiner can rely on in rejecting the claims.

Even if Schoolman is considered to be analogous art, however, there is still no suggestion to modify the Schoolman device in the manner proposed by the Examiner. As previously discussed, Schoolman discloses a general purpose clamping device, and the brief disclosure in the background of Schoolman that tissue can be retained does not provide any suggestion that the device can somehow be modified into a tissue ablation device, or for that matter, any type of tissue therapeutic device. While Ryan does disclose a tissue ablative clamping device, there is simply no suggestion in Ryan that a general purpose clamping device can somehow be modified into a tissue ablation device.

Significantly, not only does Schoolman and Ryan fail to address the problem with which Applicant was concerned, as discussed above, Schoolman and Ryan address completely different, and thus non-analogous, problems; i.e., Schoolman addresses the problem of freeing a surgeon's or medical assistant's hands, whereas Ryan addresses the problem of sealing, cauterizing,

coagulating/desiccating, or cutting vessels and vascular tissue at multiple sites (see background of Ryan). Thus, there is simply no suggestion in Ryan to modify the Schoolman device to solve the problem addressed therein.

In concluding that it would have been obvious incorporate electrodes on the clamp assembly of the Schoolman device in order to provide a tool capable of treating vessels and vascular tissue at multiple sites, the Examiner states:

Ryan discloses a multi-pronged bipolar forceps which allows a user to selectively apply electrosurgical energy to tissue to effectively seal, cauterize, coagulate and/or cut tissue during open surgical procedures and laparoscopic procedures. Schoolman discloses a flexible shaft device which can be locked in a desired shape having a live tool attachment at a distal end thereof manipulable by a user of the device. Furthermore, Schoolman teaches that an object of his invention is to provide a device capable of having a plurality of suitable devices attachable to the distal end of the shaft for carrying on a plurality of desired work processes. (see page 9 of office action).

However, no such suggestion exists in Schoolman and Ryan. The fact that Schoolman discloses that it is desirable to attach any one of a variety of tools onto the distal end of the flexible shaft, does not amount to a specific suggestion that a tissue ablation clamp be attached to the flexible shaft, and does not mean that any combination of tool with the Schoolman device would be obvious. None of the tools disclosed in Schoolman relate to the tissue ablation tools disclosed in Ryan.

Thus, Applicant submits that claims 1-5, 7-18, 29-33, and 43-45 are not obvious over the combination of Schoolman and Ryan, and as such, respectfully request withdrawal of the §103 rejections of these claims.

Claims 19-28 and 34-40

The Examiner states that the tips 90 and 92 of the Schoolman clamp assembly remain approximately parallel to one another, and that the first and second jaws of the Ryan device are

approximately parallel as they hold tissue 51 inside a patient (see paragraph bridging pages 8-9 of the Office Action). Applicant does not necessarily disagree with this. However, independent claim 19 requires the ablation device to be configured such that "the second jaw of the ablation device to remain approximately parallel to the first jaw as the second jaw is moved relative to the first jaw." Independent claim 34 requires "moving the second jaw relative to the first jaw to hold a tissue inside a patient, wherein as the second jaw is moved, the first surface of the first electrode is approximately parallel to the second surface of the second electrode." In contrast, although the jaws or tips of the Schoolman and Ryan devices may be approximately parallel to each other when clamped onto tissue, they do not remain parallel as they are moved relative to each other, as required by the claims. That is, as the jaws or tips of the Schoolman and Ryan device are opened from their completely closed position, an angle is formed between them, such that they are no longer parallel to each other.

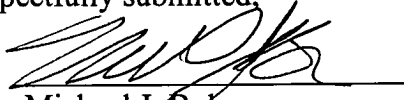
Thus, Applicant submits that claims 19-28 and 34-40 are not obvious over the combination of Schoolman and Ryan, and as such, respectfully request withdrawal of the §103 rejections of these claims.

Conclusion

Based on the foregoing, reconsideration and allowance of this application is respectfully requested. If the Examiner has any questions or comments regarding this amendment, the Examiner is respectfully requested to contact the undersigned at (714) 830-0600.

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Respectfully submitted,

By: 
Michael J. Bolan
Reg. No. 42,339

Bingham McCutchen LLP
Three Embarcadero Center, 18th Floor
San Francisco, California 94111
Customer No. 23639